

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 05-590 GMS
)	
DEXCOM, INC.,)	
)	
Defendant.)	

**DEXCOM, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STAY
PENDING RE-EXAMINATION OF THE PATENTS IN SUIT**

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NATURE AND STAGE OF PROCEEDINGS AND SUMMARY OF ARGUMENT

On August 31, 2005, DexCom moved to dismiss Abbott's Complaint for patent infringement as premature. At that time, the FDA had not approved DexCom's accused medical device, nor was approval imminent. Nearly six months later, nothing has changed. FDA approval remains uncertain, DexCom does not have an approved or marketable product, and this case is still premature.

DexCom recently has asked the U.S. Patent and Trademark Office ("PTO") to reexamine Abbott's four asserted patents. The Court should stay this case pending the outcome of proceedings in the PTO for at least three reasons:

- First, history teaches that it is highly likely the PTO will find invalid or substantially alter the claims of Abbott's asserted patents, thereby changing the legal issues in this case if not eliminating them altogether;
- Second, because this motion comes at the earliest stage of litigation—prior to completion of the pleadings and before any discovery has been taken—maximum conservation of resources will be realized by a stay; and
- Third, Abbott will not be prejudiced by a stay, particularly in light of the prematurity of its Complaint.

Neither the Court nor the parties should expend additional resources when it is uncertain which, if any, patent claims will survive the reexamination process. Because the administrative proceedings before the PTO may moot or resolve the issues presented in this case, the law firmly recommends staying this action as a prudential matter pending conclusion of the PTO's review of the asserted patents. Accordingly, if the Court is inclined

to deny DexCom's Motion to Dismiss, then the Court should stay this case pending completion of the PTO's reexamination.

STATEMENT OF FACTS

On August 11, 2005, Plaintiff Abbott Diabetes Care, Inc. ("Abbott") filed a Complaint against Defendant DexCom, Inc. ("DexCom"), alleging patent infringement and seeking declaratory relief. Abbott claims that DexCom's continuous glucose monitoring system, once approved by the FDA, will infringe four patents that Abbott recently acquired: U.S. Patent Nos. 6,175,752 ("the '752 patent"), 6,284,478 ("the '478 patent"), 6,329,161 ("the '161 patent"), and 6,565,509 ("the '509 patent") (collectively "the patents").

Two weeks later, DexCom filed its Motion to Dismiss the Complaint as premature. On September 19, 2005, Abbott moved for jurisdictional discovery and an extension of time to file its response to DexCom's motion. The Court denied Abbott's requests. Briefing on DexCom's Motion to Dismiss was complete as of September 29, 2005. The Court has yet to rule on DexCom's motion.

On January 25, 2006, DexCom filed a Request for Reexamination of the '509 patent with the U.S. Patent and Trademark Office ("PTO"). See Appendix, Ex. A (PTO Receipt of '509 patent Reexamination Request). Requests for Reexamination of the '161 patent, the '478 patent, and the '752 patent were filed on February 1, 2006. See Appendix, Exs. B-D (PTO Receipt of '161, '478 and '752 patent Reexamination Requests). Each reexamination request raised substantial questions about the validity of all independent claims in the four patents in light of previously undisclosed prior art references.

At present, no discovery has been taken. Although Abbott recently served DexCom with its first round of discovery requests and a notice of deposition, DexCom has advised

Abbott that it would seek a protective order (pursuant to Local Rule 30) and that it would file this motion to stay. DexCom has not answered the Complaint and no trial date has been scheduled.

ARGUMENT

A. The Relevant Factors All Weigh In Favor Of Staying This Case.

A district court's inherent power to control and manage its docket includes the discretion to stay proceedings. *See Pegasus Dev. Corp. v. DirecTV, Inc.*, No. 00-1020-GMS, 2003 U.S. Dist. LEXIS 8052 (D. Del. May 14, 2003). It is well-established that the PTO's reexamination of patents subject to litigation is grounds for a stay. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) ("Courts have inherent power to manage their dockets and stay . . . proceedings, including the authority to order a stay pending a conclusion of PTO reexamination."); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 606 (Fed. Cir. 1985) ("The stay of pending litigation to enable PTO review of contested patents was one of the specified purposes of the reexamination legislation.") *rev'd in non-pertinent part*, 771 F.2d 480 (Fed. Cir. 1985).

A stay order can be issued even before the PTO has granted the request for reexamination. *See, e.g., Robert H. Harris Co. v. Metal Mfg. Co.*, No. J-C-90-179, 1991 U.S. Dist. LEXIS 16086, at *5 (E.D. Ark. June 20, 1991) (stay issued pending the PTO's response to a reexamination request); *Essex Group, Inc. v. Southwire Co.*, No. C-85-1923-A, 1986 U.S. Dist. LEXIS 29761, at *3 (N.D. Ga. Jan. 31, 1986) (same).

When ruling on a motion for stay, courts generally consider the following factors: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the

case; and (3) whether discovery is complete and whether a trial date has been set.” *Alloc, Inc. v. Unilin Décor N.V.*, No. 03-253-GMS, 2003 U.S. Dist. LEXIS 11917, *4 (D. Del. July 11, 2003) (granting motion for stay); *United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F. Supp. 212, 217-18 (D. Del. 1991) (stating similar test). All three factors weigh heavily in favor of a stay pending the outcome of the PTO's administrative review of the four asserted patents in this case.

B. A Stay Will Simplify Issues, Avoid Inconsistent Rulings and Conserve the Resources of the Court and Parties.

Because the administrative proceedings before the PTO may moot or resolve the issues presented in this case, the law firmly recommends entry of a stay pending conclusion of the PTO's review of the asserted patents. Indeed, a stay is necessary here to prevent a waste of the Court's resources and those of the parties. *See Gonnocci Rev. Trust v. Three M Tool & Mach., Inc.*, No. 02-74796, 2003 U.S. Dist. LEXIS 24423, at *12-13 (E. D. Mich. Oct. 7, 2003) (stay appropriate where considerable time and resources already spent, but much work remaining, including responses and judicial review of two summary judgment motions and preparation for trial); *Bausch & Lomb, Inc. v. Alcon Lab., Inc.*, 914 F. Supp. 951, 953 (W.D.N.Y. 1996) (granting stay pending reexamination to avoid wasting “the time, resources, and significant efforts of all those involved”).

“One purpose of the reexamination procedure is to eliminate trial of that issue (when the [patent] is canceled) or to facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceeding).” *Gould v. Control Laser Corp.*, 705 F.2d 1340, 1342 (Fed. Cir.), *cert. denied*, 464 U.S. 935 (1983). Congress specifically “instituted the reexamination process to shift the burden of reexamination of patent validity from the courts to the PTO.” *Canady v. Erbe Elektromedizin*

GmbH, 271 F. Supp. 2d 64, 78 (D. D.C. 2002). Continued litigation in the face of a pending reexamination proceeding is fraught with the potential for the waste of judicial resources given that, “[g]enerally speaking, the PTO invalidates 10% of the patents it reexamines and amends the claims in 64%.” *Tap Pharma Prods, Inc. v. Atrix Labs., Inc.*, 70 U.S.P.Q. 2d 1319, 1320 (N.D. Ill. 2004). And the courts should “not expend unnecessary judicial resources by attempting to resolve claims which may be amended, eliminated, or lucidly narrowed by the patent reexamination process and the expertise of its officers.” *Hewlett-Packard Co. v. Acuson Corp.*, No. C-93-0808 MHP, 1993 U.S. Dist LEXIS 6449, * 4 (N.D. Cal. May 6, 1993) (citation omitted). For this reason, the courts regularly stay cases pending the completion of reexamination proceedings “to wait for reexamination results that will simplify litigation by eliminating, clarifying, or limiting the claims.” *Canady*, 271 F. Supp. 2d at 68, citing *Ethicon*, 849 F.2d at 1428; *see also* *Whitley v. Nike, Inc.*, 54 U.S.P.Q. 2d 1124, 1125 (D. Or. 2000) (there exists a “liberal policy in favor of granting motions to stay proceedings pending the outcome of reexamination proceedings,” quoting *ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994)).

There are three possible outcomes of a reexamination: the PTO may cancel, amend or confirm the issued claims. If the PTO cancels all the asserted claims, then Abbott no longer has patents on which it may proceed against DexCom. If that occurs and this Court does not stay this case, then all of the time and cost expended by the Court and the parties will have been wasted. If the claims are amended by the PTO, then the issues and scope of discovery will change. Moreover, changes to the claims likely will affect both the claim construction process and outcome. First, the reexamination process will create additional intrinsic evidence—in the form of new prosecution history—that the Court will need to

consider in construing the claims. Second, if a stay is not entered and discovery and claim construction proceed, subsequent changes to the claims as a result of the reexamination process will necessitate that the Court revisit claim construction.¹ Absent a stay, the benefits of this Court's practice of resolving claim construction at an early stage will be lost.

As DexCom informed the PTO in its reexamination requests, there is strong evidence that claims in all four patents are rendered obvious or anticipated by prior art references. Should the PTO grant DexCom's reexamination requests, it is likely that all or some of the claims will either be cancelled or amended. Based on the PTO's own statistics, there is a significant likelihood that the PTO will order reexamination of Abbott's four patents. In 2004, the PTO granted 408 requests for reexamination *while denying only 11*. See Appendix, Ex. E (USPTO 2004 Performance and Accountability Report, Table 13A). Similarly, during 2002 and 2003, the PTO granted a total of 624 requests for reexamination while denying only 29. *Id.* In fact, from 1981 through 2004 91% of all requests for reexamination have been granted. Appendix, Ex. F (Ex Parte Reexamination Filing Data - December 31, 2004, ¶ 5). And of those reexaminations actually granted between 1981 and 2004, 74% have resulted in either the cancellation of all claims or at least some claim changes. *Id.* (¶ 9).

Entry of a stay is consistent with the purposes of the reexamination statute. 35 U.S.C. § 301 *et seq.* As discussed above, the statute was designed, in part, to eliminate trials on patent claims that are cancelled or substantially narrowed. See *Gould*, 705 F.2d at 1342. Accordingly, there is a "liberal policy in favor of granting motions to stay proceedings

¹ Even in the unlikely event that the PTO confirms the claims of Abbott's patents, any new prosecution history (*i.e.*, arguments made by Abbott to defeat obviousness or anticipation rejections made by the PTO) will likely affect the proper construction of the asserted claims.

pending the outcome of USPTO reexamination or reissuance proceedings.” *ASCII Corp.*, 844 F. Supp. at 1381. As this Court noted in *Pegasus*, a stay pending reexamination is beneficial not only because it provides courts with the PTO’s expertise in evaluating the prior art; it also streamlines the litigation process in the following ways:

(1) many discovery problems relating to the prior art may be alleviated; (2) the record of the reexamination likely would be entered at trial, reducing the complexity and length of the litigation; (3) the issues, defenses, and evidence will be more easily limited in pre-trial conferences following a reexamination; (4) the outcome of the reexamination process may encourage a settlement without further involvement of the court; and (5) if the patent is declared invalid, the suit likely will be dismissed as to that patent. These efficiencies will result in a reduced cost of litigation for the parties and more effective utilization of the limited resources of the court.

Pegasus, 2003 U.S. Dist. LEXIS 8052, at *6 (internal citations omitted). For all of these reasons, the Court should stay this case to conserve the resources of the Court and parties.

C. Courts Routinely Grant Stays At This Early Stage In The Proceedings.

Courts routinely stay matters in favor of patent reexamination where, as here, the case is in its initial stages and no discovery has occurred. *E.g.*, *Werre v. Battenfeld Techs., Inc.*, No. 03-1471-AA, 2004 U.S. Dist. LEXIS 23250, *3 (D. Or. Nov. 9, 2004); *Tap Pharma*, 70 U.S.P.Q. 2d at 1320; *In re Laughlin Prods, Inc. Patent Litigation*, 265 F. Supp. 2d 525, 532 (E.D. Pa. 2003); *Methode Elecs., Inc. v. Infineon Techs. Corp.*, No. C 99-21142 JW, 2000 U.S. Dist. LEXIS 20689, *6-*7 (N.D. Cal. Aug. 7, 2000); *ASCII Corp.*, 844 F. Supp. at 1381.

The rationale for staying cases in this posture—that is, when the case is in its early stages—is that the “patent reexamination legislation clearly favored the liberal grant of stays by the district courts when patents are submitted for reexamination as a mechanism for

settling disputes quickly and less expensively and for providing the district courts with the expertise of the patent office.” *Lentek Int’l, Inc. v. Sharper Image Corp.*, 169 F. Supp. 2d 1360, 1362 (M.D. Fla. 2001) (multiple citations omitted). Where a party acts early in patent litigation to seek reexamination by the PTO, the expertise and cost efficiencies for which the reexamination procedure was created can best be effectuated.

Courts have granted stays, even where much time and money have already been spent, in order to prevent further waste of resources. See *Gould*, 705 F.2d at 1341-42 (upholding a 1983 stay of litigation pending since 1979); *Middleton, Inc. v. Minnesota Mining and Mfg. Co.*, No. 4:03-cv-40493, 2004 U.S. Dist. LEXIS 16812, at *4, 22 (S. D. Iowa Aug. 24, 2004) (granting a stay eight years into the litigation and two months before trial); *Bausch & Lomb*, 914 F. Supp. at 952-53 (granting stay despite the fact that discovery was complete and a trial date set); *Robert H. Harris Co. v. Metal Mfg. Co.*, No. J-C-90-179, 1991 U.S. Dist. LEXIS 16086, at *9 (E.D. Ark. June 20, 1991) (stay granted where case set for trial the next month); *Emhart Indus., Inc. v. Sankyo Seiki Mfg. Co.*, No. 85 C 7565, 1987 U.S. Dist. LEXIS 15033, at *1 (N.D. Ill. Jan. 30, 1987) (granting defendant’s motion to stay patent infringement action even though all discovery completed); *Loffland Bros. Co. v. Mid-Western Energy Corp.*, 225 U.S.P.Q. 886 (W.D. Okla. 1985) (stay granted despite the fact that one trial date had already been extended).

The facts and procedural history of this case justify a stay. Abbott commenced this action only six months ago. Since then, there has been almost no activity in the case while the parties await the Court’s decision on DexCom’s Motion to Dismiss. There has been no document production. No depositions have been taken. No written discovery responses

have been served. The Court has not begun to engage in claim construction. Indeed, no answer to the Complaint has been filed.

Staying the case early in the litigation process will maximize efficiency and promote judicial economy. In *Alloc*, this Court entered a stay where, as here, discovery had not begun, the discovery schedule had not been entered, and no trial date had been set. *Alloc*, 2003 U.S. Dist. LEXIS 11917, at *8 (“stay will be entered before any party incurs substantial litigation-related expenses”). Likewise, by granting a stay in this case, the Court will conserve the resources of all involved.

D. A Stay Will Not Prejudice Abbott.

Abbott will not suffer any substantial prejudice by a stay. First, as DexCom demonstrated in its Motion to Dismiss, this case is premature and lacks subject matter jurisdiction. In any event, *if* this dispute becomes ripe, and *if* the PTO does not invalidate or alter the claims of Abbott’s patents, then Abbott’s legal remedy will not be affected. *See Sulzer Inc. v. Black Clawson Co.*, No. 93 Civ. 8721, 1995 U.S. Dist. LEXIS 8328, at *3 (S.D.N.Y. June 14, 1995) (“The defendant will not be prejudiced by the stay and the stay will conserve the resources of the parties and promote the efficient resolution of this case.”). Moreover, any narrowing of the issues due to reexamination will benefit Abbott as much as DexCom, by minimizing needless waste of resources.

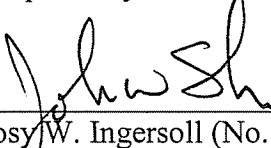
In contrast, allowing this case to proceed in conjunction with the PTO proceedings would not only forgo efficiencies but would also create a substantial risk of multiple, inconsistent rulings. Permitting this case to continue in parallel with the PTO reexaminations would create a substantial risk of inconsistent rulings or this Court’s issuing advisory opinions. *See Gioello Enterprises Ltd. v. Mattel, Inc.*, No. C.A. 99-375 GMS, 2001

WL 125340 (D. Del. Jan. 29, 2001) at *1 ("Not staying the proceedings runs the risk of inconsistent adjudications or issuance of advisory opinions."). While the PTO must conclude its administrative review, this Court has the discretion to stay this litigation. Thus, only the Court can take steps to avoid that potential conflict. *Id.* at *2 ("Since the PTO cannot stay the reexamination once a request has been granted, the court's issuance of a stay is the only way to avoid the potential for conflict.").

CONCLUSION

This Court lacks jurisdiction to preside over premature litigation where, as here, the FDA has not approved the accused invention and FDA approval is not imminent. Moreover, the scope and validity of the patent claims will remain uncertain until the PTO issues its decisions. Therefore, efficient administration of justice and the purpose of the reexamination statute mandate a stay. If the Court is inclined to deny DexCom's Motion to Dismiss, it should stay the case rather than proceed with costly, time-consuming and potentially unnecessary litigation.

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CERTIFICATE OF SERVICE

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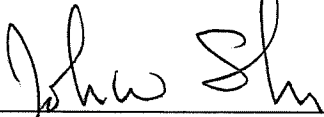
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